did not have the disease, demonstrated by a crude relative risk of 6.06 in England (37.6% vs. 6.2%), 2.68 in The Netherlands (19.0% vs. 7.1%), and 1.97 in Spain (14.9% vs. 7.5%). When controlling for covariates, predictive models found a considerable impact of hospital-onset CDI on mortality with odds ratios of 2.57 for England (p<0.001), 1.88 for The Netherlands (p<0.001) and 1.33 for Spain (p<0.001). **CONCLUSIONS:** This research demonstrates the significant impact of CDI on hospital mortality and the need for more preventative measures within the hospital setting. Further research using death certificate data could improve the predictive results of models by ensuring that causal effects of CDI are accurately accounted for.

PGI2

RULING OUT IBD IN THE UNITED KINGDOM AND SPAIN: IS THE USAGE OF F-CALPROTECTIN IN PRIMARY CARE COST-EFFECTIVE?

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OBJECTIVES: The inflammatory bowel diseases (IBD) are characterized by chronic inflammation of the gastrointestinal tract; the irritable bowel syndrome (IBS) is a functional disorder (prevalence 10%-20%). They present overlapping symptoms, making diagnosis difficult in primary care. Endoscopy is the gold standard for IBD, but it often turns negative due to IBD's low prevalence, it is expensive, uncomfortable and risky for the patient. F-Calprotectin is a marker of intestine inflammation: as IBD patients exhibit levels higher than the general population and IBS patients, F-Calprotectin can be used to rule out IBD. The only CE evaluation on F-Calprotectin has been published by NHS (CEP09041, 2010); based on new evidence, we propose a refined model to evaluate the CE of F-Calprotectin compared to the standard pre-endoscopic serologic test (CRP+ESR) to distinguish IBD from IBS in the UK and Spain. **METHODS:** F-Calprotectin sensitivity (0.96) and specificity (0.96) were evaluated from a meta-analysis performed in March 2013; CRP+ESR sensitivity (0.35) and specificity (0.73), and the costs come from CEP09041. Published HRQoL values for IBD and IBS were transformed in QALYs with transfer-to-utility techniques. The outcomes included cost savings, cost per QALY. Uncertainty was addressed with a probabilistic sensitivity analysis. **RESULTS:** Results for UK show that F-Calprotectin is CE with respect to CRP+ESR: a) it results in more corrected IBD diagnoses at a lower price (it costs 113£ and 85€ less per patient); b) it reduces the number of unnecessary endoscopies, increasing the number of correctly diagnosed IBD (N=59) and IBS (N=195) patients; c) it brings about a QALY gain per patient equal to 0.0034QALYs; in the UK, the ICER of the CRP+ESR diagnostic strategy is 47,783£ (25,941€ for Spain), falling well outside the cost-effectiveness bounds (20,000–30,000£ per additional QALY). **CONCLUSIONS:** F-Calprotectin is CE to rule out IBD in primary care in UK and Spain.

PGI3

DIAGNOSIS OF PANCREATIC EXOCRINE INSUFFICIENCY IN CHRONIC PANCREATITIS, PANCREATIC CANCER AND GASTROINTESTINAL OR PANCREATIC SURGERY PATIENTS: A SYSTEMATIC LITERATURE REVIEW AND EXPERT CONSENSUS ON THE ACCURACY OF DIAGNOSTIC TEST USED IN SPAIN

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OBJECTIVES: To systematically appraise the literature on the accuracy of four widely used tests to diagnose Pancreatic Exocrine Insufficiency (PEI) secondary to chronic pancreatitis (CP), gastrointestinal/pancreatic surgery or pancreatic cancer in Spain, namely: coefficient of fat absorption (CFA); mixed 13C-triglyceride breath test (MTG); fecal elastase-I (FE-I); and serum nutritional markers (SNM). **METHODS:** A systematic review of the literature (March, 2013) was performed (*MedLine/PubMed*, Cochrane Library, CRD, MEDION, ARIF, MEDES, IBECS, ISI WOK, SCOPUS), based on the Cochrane and NHS Centre for Reviews and Dissemination recommendations for reviewing diagnostic test accuracy studies. Expert validation of the review strategy and results were achieved by two consensus meetings. **RESULTS:** Out of 13.379 publications, 16 from the systematic search and 3 from hand-search were reviewed: 11 in CP and 8 in cancer/surgery patients. Fourteen of these used the secretin/cerulein test as the reference standard. According to experts, CFA is the gold standard for PEI diagnosis (assumed accuracy 100%). 4 publications using CFA as the reference standard were selected: FE-I sensitivity and specificity in 58 CP (cutoff <218μg/g) and 40 cancer/surgery patients (cutoff 200μg/g) were 68% and 98%, and 91% and 35%, respectively. MTG was ≥90% sensitive and specific in all populations (63 patients), experts considered this a good reference standard. Sensitivity and specificity for SNM vs. MTG were 80% and 81%, respectively and considered by experts as similarly accurate in the cancer/surgery population. **CONCLUSIONS:** This is the first systematic review to confirm the accuracy of four diagnostic tests for PEI in CP and cancer/surgery patients, with the final selection of results being based on expert consensus to ensure that the data are representative of Spanish clinical practice. These data, together with resource use and cost information from clinical practice will feed an economic tool to assess the cost of PEI diagnosis in Spain.

PGI4

NETWORK META-ANALYSIS OF APPROVED BIOLOGIC INTERVENTIONS FOR THE INDUCTION OF RESPONSE IN ULCERATIVE COLITIS

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OBJECTIVES: To evaluate the comparative efficacy of approved biologic treatments for ulcerative colitis (UC), with a focus on golimumab(GOL), adalimumab(ADA), and infliximab(IFX) in the induction periods of clinical trials. **METHODS:** A systematic literature review was performed to identify relevant randomized controlled trials (RCTs). Data were extracted on study design and patient characteristics. Endpoints concerning efficacy were evaluated using network meta-analyses. Clinical response was defined as a decrease in Mayo score of ≥30% and ≥3 points, accompanied by a decrease in rectal bleeding score of ≥1 point or rectal bleeding score of 0 or 1. Clinical remission was defined as a total Mayo score of 2 points or lower, with no individual subscore exceeding 1 point. Mucosal healing was defined as absolute subscore for endoscopy of 0 or 1. Bayesian network meta-analyses (NMA) were conducted to evaluate each efficacy endpoint for TNF-naïve patients at the end of induction. All analyses were conducted using the OpenBUGS software package. **RESULTS:** Six RCTs were identified from the literature. Similar clinical response was observed between the IFX and GOL treatment regimens (IFX 5mg: OR=2.74, 95%CrI [1.48-5.1], IFX 10mg: 2.54 [1.37-4.73], GOL 200/100mg: OR=1.7 [0.93-3.14], GOL 400/200mg: 1.95 [1.05-3.58]) when compared to ADA 160/80mg. These similarities were also seen for mucosal healing (IFX 5mg: 2.66 [1.43-4.94], IFX 10mg: 2.57 [1.38-4.77], GOL 200/100mg: 1.54 [0.83-2.85], GOL 400/200mg: 1.68 [0.91-3.10]). IFX demonstrated slightly greater clinical remission than GOL (IFX 5mg: 1.96 [0.80-4.65], IFX 10mg: 1.51 [0.61-3.62], GOL 200/100mg: 1.55, 0.59-4.06], GOL 400/200mg: 1.47 [0.56-3.84]) when compared to ADA 160/80mg. **CONCLUSIONS:** The NMA allowed the estimation and comparisons of clinical response, remission, and mucosal healing of interventions for UC evaluated in different RCTs. The findings suggest that the greatest induction of response in moderate to severe UC patients is most likely achieved with IFX and GOL compared to ADA.

PGI5

NETWORK META-ANALYSIS OF APPROVED BIOLOGIC INTERVENTIONS FOR THE MAINTENANCE OF RESPONSE IN ULCERATIVE COLITIS

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OBJECTIVES: To evaluate the comparative long-term efficacy of approved biologic treatments for ulcerative colitis (UC), with a focus on golimumab(GOL), adalimumab(ADA), and infliximab(IFX). **METHODS:** A systematic literature review identified 4 randomized controlled trials (RCTs) assessing the efficacy of IFX (5mg, 10mg), ADA (160/80/40mg) and GOL (100mg, 50mg) as maintenance treatment for moderate to severe UC. Data were extracted on study design and patient characteristics. Endpoints concerning efficacy were evaluated using network meta-analyses (NMA) within a Bayesian framework. Analyses were conducted to evaluate sustained response to therapy at both the mid-point (week 30/36) and completion (week 52/54/60) of each trial. An additional sub-analysis was conducted because the PURSUIT trial design included a re-randomization of induction responders to placebo, GOL 50mg or GOL 100mg. This sub-analysis was limited to patients who received an induction regimen of GOL 200/100mg followed by 100mg during the maintenance period and induction non-responders who received 100mg as per protocol. All analyses were conducted using the OpenBUGS software package. **RESULTS:** 4 RCTs were identified from the literature. Overall, IFX and GOL showed greater sustained response, remission and mucosal healing when compared to ADA 160/80/40mg. Between IFX and GOL, IFX doses showed greater remission at trial's completion (IFX5mg OR=2.04, 95%CrI 0.6-7.03; IFX10mg 1.96, 0.6-6.8; GOL50mg 1.24, 0.4-3.9; GOL100mg 1.79, 0.6-5.4), response (IFX5mg 1.88,0.8-4.4; IFX10mg 1.73, 0.7-4.1; GOL50mg, 1.38, 0.6-3.1; GOL100mg 1.45, 0.6-3.3) and mucosal healing (IFX5mg 1.51,0.7-3.4; IFX10mg 1.53, 0.7-3.5; GOL50mg, 1.38, 0.6-3.3; GOL100mg 1.38, 0.6-3.2. During the sub-analyses, GOL100mg and both IFX doses demonstrated greater sustained response and sustained remission when compared to ADA 160/80/40mg. Sustained mucosal response increased for IFX 5mg and IFX10mg but decreased for GOL100mg. **CONCLUSIONS:** Based on indirect comparison of RCT evidence, IFX and GOL are more efficacious to induce and maintain long term response than ADA among moderate to severe UC patients.

PGI6

A SYSTEMATIC REVIEW OF ANTIDEPRESSANTS IN IRRITABLE BOWEL SYNDROME: A QUALITATIVE ANALYSIS

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OBJECTIVES: To systematically identify and review published evidence on the efficacy of antidepressants (tricyclic antidepressants (TCA) and selective serotonin inhibitors (SSRI)) for irritable bowel syndrome (IBS). **METHODS:** A systematic search of the medical literature was conducted using PubMed, Embase, and Cochrane databases. Search terms included 'irritable bowel syndrome', 'spastic colon', 'irritable colon', 'functional diseases, colon' and a mixture of agent terms – including antidepressants, tricyclic, and SSRIs. Randomised placebo-controlled trials evaluating the efficacy of antidepressants (SSRIs and TCAs) in adult patients with IBS were eligible for inclusion. Exclusion criteria included absence of placebo arm, patients<18 years of age, and dual publication. **RESULTS:** A total of 628 unique titles and abstracts were retrieved; 579 records were excluded upon title (or abstract) review and 31 upon full-text review. The final review included 17 studies, 10 reporting on TCAs, 6 on SSRIs, and 1 comparing both an SSRI and a TCA vs. placebo, and assessed the methodological compliance of each included study with that used in regulatory submissions. In these studies, the majority of patients had diarrhea, and only one study, (on SSRIs) reported specifically on IBS-C. Treatment duration ranged from 4-12 weeks. A range of outcomes were reported, most commonly global symptom relief, and improvements in abdominal pain/discomfort. Three studies reported on quality of life, while no studies reported specifically on treatment satisfaction. Most outcomes did not align well with those now required for FDA and EMA regulatory approval. Across all studies, patient dropouts were common, and reporting on per-protocol and intention-to-treat (ITT) populations varied and in many cases was not explicitly reported. **CONCLUSIONS:** The evidence base was of low quality, making estimates of effect very uncertain. Data for the efficacy of antidepressants in IBS subtypes is especially limited. Further studies are required to support the off-label use of antidepressants in IBS-C.